

Office Action Summary

Application No.

08/612,661

Applicant(s)

Christensen et al.

Examiner

Ardin Marschel

Group Art Unit

1809

☒ Responsive to communication(s) filed on 5-7-97☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-8 and 11-21 is/are pending in the application.

~~Of the above, claim(s) 9 and 10 is/are withdrawn from consideration.~~

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-8 and 11-21 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' arguments, filed 5/7/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Applicant's election of Group I (claims 1-8, now claims 1-8 and 11-21) in Paper No. 11, filed 5/7/97, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the computer readable form contains errors as summarized on the sequence error listing enclosed with the previous office action, mailed 12/3/96. Although applicants state in the REMARKS, filed 5/7/97, that a replacement copy of the computer readable form has been submitted, none has been received as of the mailing of this office action. It is noted that the errors in the sequence listing also requires a replacement to the sequence listing that is amended into the specification. Applicants did not state that such an amendment has been submitted nor has one been filed in the instant

application. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to nucleic acid mimics that are formable via either peptide bond type linkages, vinyl polymerization type linkages, or phosphodiester analog linkages. This is a relaxation of this requirement considering the summary pointed to by applicants in WO 86/05518. Consideration of the instant specification reveals that the only chemistry that is described is the linking of monomers into nucleic acid polymers via peptide bond formation chemistry. It is however noted that vinyl monomeric type polymerization methods with nucleic acid bases as side groups is well known in the art to make nucleic acid mimics. This rejection is reiterated and maintained as given in the previous office action, mailed 12/3/96. Applicants argue that pages 2-3 of WO 86/05518 supports the well known synthesis of a variety of non-natural backbones for nucleic acid binding polymers. This has been persuasive for the above added scope as summarized above

but is not persuasive regarding a very broad scope of the instant claims directed to the broadly stated "non-naturally occurring backbone structure" as given in claim 1, for example. Only a limited list of non-natural backbones are given in said WO 86/05518 with the allegation that others are possible. Allegations fall short of clear, concise, and exact description as required for an enabling disclosure. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Consideration of claims 11-19, newly submitted, reveals that the polymer cited therein terminates at one end with the moiety D^{n-1} with Q at the other terminus. Consideration of the synthetic methodology described in the specification reveals that these embodiments are linked together from monomers as shown in Figure 1, for example. These monomers contain termini for linkage into polymers wherein one is of the amino type and the other is of the carboxyl type. Therefore, none of these monomers terminate with a structure as instantly claimed as D^{n-1} with the exception of the D^{n-1} selection wherein it is CR^6R^7 wherein further at least one of R^6 or R^7 is the selection NR^3R^4 . Therefore, there is no synthetic methodology that is instantly supplied that results in the chemical structure now claimed in claims 11-21 with a terminus of the D^{n-1} type beyond the above amino type terminus selection. Given this selection requirement the Q terminus will also be restrained compared to the present Q scope. Therefore, these claims 11-19 lack enablement beyond the above described scope due to a lack of an instantly disclosed method of making the therein

claimed compounds with the exceptions noted above. Similarly, claims 20 and 21 terminate with termini that lack enablement considering the synthetic monomers that are instantly disclosed. This rejection is necessitated by amendment.

Claims 11-21 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the above objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Summerton et al.

This rejection is maintained and reiterated from the previous office action, mailed 12/3/96, and further supported by specific disclosures in the reference as necessitated by amendment. Applicants have amended the instant claims to require the presence of a target molecule with the nucleic acid mimic in an admixture and argue that this overcomes the rejection. In response the reference is noted as citing the practice of utilizing nucleobases with sterically bulky groups on page 48, lines 1-34, to affect the binding affinity to target molecules. This binding affinity result inherently occurs during

hybridization methodology wherein target molecule(s) is(are) present thus again reading on the instant claims.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

August 4, 1997

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800